

DEPARTMENT OF HEALTH AND HUMAN SERVICES

AUG 25 1997

Vickie Forster
Registration Specialist
Regulatory Affairs-Biotechnology
AgrEvo USA Company
Little Falls Centre One
2711 Centerville Road
Wilmington, DE 19808

Dear Ms. Forster:

This letter is in regard to AgrEvo's consultation with the Food and Drug Administration (FDA) (Center for Veterinary Medicine and Center for Food Safety and Applied Nutrition) on genetically modified canola, transformation event T45 and progeny derived therefrom. According to AgrEvo, the new canola variety has been rendered tolerant to the herbicide glufosinate ammonium by expression of a synthetic version of a phosphinothricin-N-acetyltransferase gene derived from *Streptomyces viridochromogenes*.

As part of bringing AgrEvo's consultation regarding this product to closure, AgrEvo submitted a summary safety and nutritional assessment of canola containing transformation event T45, and supporting documents, on May 29, 1997.

This communication informed FDA of the steps taken by AgrEvo to ensure that this product complies with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment you have conducted, it is our understanding that AgrEvo has concluded that this new canola variety is not materially different in composition, safety, or any other relevant parameter from canola varieties currently on the market, and that it does not raise issues that would require premarket review or approval by FDA. All materials relevant to this notification have been placed in a file designated BNF0046. This file will be maintained in the Office of Premarket Approval.

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Based on the information AgrEvo has presented to FDA, we have no questions concerning this product at this time. However, as you are aware, it is AgrEvo's continued responsibility to ensure that food and feed derived from canola containing transformation event T45 are safe, wholesome, and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

/s/

Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition